

Remarks/Arguments

Claims 1-10 and 12 are pending. By this amendment, Applicants have canceled claims 11 and 13-18 without prejudice or disclaimer. Applicants reserve the right to pursue the canceled claims in a divisional or continuation application(s).

Applicants have amended claims 1 and 7 to recite “wherein said elevated serum concentration of the UGT1A1 substrate is not caused by administration of atazanavir.” Applicants have also amended claim 5 to recite “wherein said unconjugated hyperbilirubinemia is not caused by administration of atazanavir.” Applicants respectfully submit that these amendments are supported at least by original claims 1, 5 and 7 and page 4, lines 7-20, of the specification. Applicants also respectfully submit that one of ordinary skill in the art can reasonably conclude that, at the time the present application was filed, Applicants had possession of the methods recited in claims 1 and 7, where the elevated serum UGT1A1 substrate level(s) or unconjugated hyperbilirubinemia is not caused by administration of atazanavir.

Applicants have also amended claim 7 to remove the phrase “upon administration of an active pharmaceutical ingredient,” and replace the term “co-administering” with “administering.” These amendments are supported at least by original claim 7.

In addition, Applicants have amended claim 9 to recite “wherein said elevated serum concentration of the UGT1A1 substrate is a result of administration of an active pharmaceutical ingredient to the subject.” Furthermore, Applicants have amended claim 9 to delete the term “atazanavir,” and replace the phrase “consisting essentially of” with “consisting of.” These amendments are supported at least by original claims 7 and 9.

Moreover, Applicants have amended claim 10 to make it dependent from claim 9, instead of claim 7. This amendment is supported at least by original claims 7, 9 and 10.

Applicants have further amended the Title of the specification.

Applicants respectfully submit that the amendments to the specification and claims do not introduce new matter. Accordingly, entry of these amendments is respectfully requested.

Claim Rejections Under 35 U.S.C. §112, First Paragraph

On pages 2-5, the Office Action rejects claims 7, 8 and 10-12 under 35 U.S.C. §112, first paragraph, as being not enabled. Applicants respectfully traverse the rejection.

Applicants have canceled claim 11 without prejudice or disclaimer, thereby rendering the rejection of claim 11 moot.

Applicants respectfully submit that claim 7 does not claim “an active pharmaceutical ingredient” capable of causing an elevated serum level of an UGT1A1 substrate. Instead, claim 7 recites a method for treating diseases/disorders/adverse effects caused by an elevated serum concentration of an UGT1A1 substrate. Therefore, to practice the recited method, one of ordinary skill in the art does not need to know which “active pharmaceutical ingredient” actually causes the elevated serum concentration of the UGT1A1 substrate. As long as there is an elevated UGT1A1 substrate serum level, one of ordinary skill in the art can use the recited method to treat diseases, disorders or adverse effects caused by such an elevated level. Accordingly, Applicants respectfully submit that one of ordinary skill in the art do not need to “run tests on an finite, but astronomical, number of possible compounds” in order to make and use the claimed method.

Based on the foregoing, Applicants respectfully submit that claim 7 satisfies the enablement requirement. Reconsideration and withdrawal of the §112 rejection of claim 7 are, therefore, respectfully requested.

Because claims 8, 10 and 12 depend from claim 7, Applicants respectfully submit that these claims also satisfy the enablement requirement. Reconsideration and withdrawal of the §112 rejection of these claims are also respectfully submitted.

Claim Rejections Under 35 U.S.C. §112, Second Paragraph

On pages 5-6, the Office Action rejects claim 9 under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the term “consisting essentially of.” Applicants have amended claim 9 to replace “consisting essentially of” with “consisting of.” Applicants believe that this amendment obviates the Examiner’s rejection. Accordingly, reconsideration and withdrawal of the §112 rejection of claim 9 are respectfully requested.

On pages 6-7, the Office Action rejects claims 13-18 under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have canceled claims 13-18 without prejudice or disclaimer, thereby rendering the rejection of these claims moot.

Claim Rejections Under 35 U.S.C. §102

On pages 8-10, the Office Action rejects claims 1-9 and 11-18 as being anticipated by Agarwala *et al.* Applicants respectfully traverse the rejection.

Applicants respectfully submit that Agarwala *et al.* neither teaches nor suggests the use of ritonavir to treat elevated UGT1A1 substrate levels or unconjugated hyperbilirubinemia. To expedite the prosecution of this application, Applicants have amended claims 1 and 7 to recite “wherein said elevated serum concentration of the UGT1A1 substrate is not caused by administration of atazanavir.” Applicants have also amended claim 5 to recite “wherein said unconjugated hyperbilirubinemia is not caused by administration of atazanavir.” Applicants believe that these amendments overcome the Examiner’s rejection of claims 1, 5 and 7. Reconsideration and withdrawal of the §102 rejection of these claims are therefore respectfully requested.

Because claims 2-4 depend from claim 1, claim 6 depends from claim 5, and claim 8 and 12 depend from claim 7, Applicants respectfully submit that claims 2-4, 6, 8-10 and 12 are also patentable over Agarwala *et al.* Reconsideration and withdrawal of the §102 rejection of these claims are also respectfully requested.

As noted, Applicants have canceled claims 11 and 13-18 without prejudice or disclaimer, thereby rendering the rejection of these claims moot.

On page 10, the Office Action further rejects claims 13-18 as being anticipated by Norbeck *et al.* Applicants have canceled claims 13-18 without prejudice or disclaimer, thereby rendering the rejection moot.

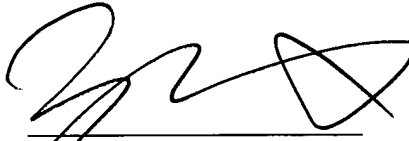
On page 8, the Examiner requests Applicants to submit another copy of Agarwala *et al.* because the original copy is allegedly of poor quality. After reasonable efforts, Applicants have not been able to obtain another copy of Agarwala *et al.* that has improved quality. However, Applicants enclose herewith a copy of a summary of Agarwala *et al.*. See Exhibit A. This summary was published as Abstract H-1716 in PROGRAM AND ABSTRACTS OF THE 42ND INTERSCIENCE CONGRESS ON ANTIMICROBIAL AGENTS AND CHEMOTHERAPY (September 27-30, 2002; San Diego, California).

Conclusion

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Although Applicants believe that the fees attached herewith are correct, the Commissioner is hereby authorized to charge any payment deficiency to deposit account number 01-0025 referring to docket number 7050.US.O2.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' representative designated below.

Respectfully submitted,



Xu Zhang
Lim. Rec. No. L0116

Date: October 24, 2006

ABBOTT LABORATORIES
Telephone: (847) 935-1133
Facsimile: (847) 938-2623